STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 123033-001

Blue Cross Blue Shield of Michigan Respondent

Issued and entered this 4th day of January 2012 by R. Kevin Clinton Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On August 24, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The Commissioner reviewed the request and accepted it on August 31, 2011.

The Petitioner has health care coverage through an underwritten group. The Petitioner's benefits are defined in BCBSM's *Community Blue Group Benefits Certificate* (the certificate). The Commissioner notified BCBSM of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on September 2, 2011.

Because the case involves medical issues, the Commissioner assigned the case to an independent medical review organization. The reviewer's analysis and recommendations were submitted to the Commissioner on September 15, 2011. A copy of the complete report is being provided to the parties with this Order.

II. FACTUAL BACKGROUND

The Petitioner is a thirty-three year old male who was admitted to the hospital on February 17, 2011, after he experienced a near loss of consciousness at work. He has a history of hypertension, hypercholesterolemia, anxiety and obesity. His doctor prescribed mobile cardiac

outpatient telemetry (MCOT) services from March 4, 2011 to April 17, 2011, to monitor his cardiovascular functions. MCOT includes two elements: a device worn by a patient which transmits signals to a monitoring station where the cardiovascular functions are read and evaluated. Both the device and monitoring services are provided by an XXXXX company, XXXXX, Inc. The charge for the MCOT services is \$4,500.00.

BCBSM denied coverage for the services, arguing that the device is investigational and therefore not a benefit under the *Community Blue* certificate.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference and issued a final adverse determination dated July 8, 2011, affirming its position.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's heart monitoring as investigational?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's representative, in the request for external review wrote:

- ... Contrary to the finding in the Plan Denial Letter, the Services are well-established as clinically effective and are a covered Plan benefit that were medically necessary and appropriate for this Patient. This conclusion is supported by the clinical determinations of the Ordering Physician, the standards of care in the medical community, studies in peer-reviewed and other medical literature, the terms of the Patient's Plan coverage and applicable law.
- ... This technology was approved by the FDA in November 1998 and is covered by the Level 1CPT codes 93229 for the technical component and 93228 for the professional component. Mobile cardiovascular telemetry services for the indication involved in this case have now been used effectively by the medical community in the United States for over a decade, and the health plans that cover this clinically valuable service for this indication include, among others, Medicare ... Tricare, Highmark BC/BS, Independence BC/BS, Wellmark BCBS, Aetna, Cigna, and Humana.

BCBSM's Argument

BCBSM states that the Petitioner's health plan requires that a service be medically necessary in order to be a covered benefit. The plan excludes coverage for services considered to be experimental or investigational.

In the final adverse determination, BCBSM's analyst wrote:

... I considered all of the facts and information relevant to your appeal; however, I confirmed our denial determination is correct. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that it is investigational.

* * *

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. As established technology means that the safety and effectiveness have been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

As indicated on Page 6.3 of your Community Blue Group Benefits Certificate, "We do not pay for experimental treatment (including drugs or devices) or services related to experimental treatment . . ." Page 7.9 of the same certificate defines experimental treatment as "Treatment that has not been scientifically proven to be as safe and effective for the treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as experimental services."

Commissioner's Review

The question of whether the Petitioner's heart monitor was investigational/experimental for treatment of his condition was presented to an independent medical review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with subspecialties in cardiovascular disease and clinical cardiac electrophysiology. The reviewer is a clinical assistant professor in the division of cardiology at a university school of medicine, a Fellow of the American College of Cardiology, and is published in peer-reviewed medical literature. The reviewer is familiar with the medical management of individuals with the Petitioner's condition. The IRO reviewer's report includes the following analysis and conclusion:

Clinical Rationale for the Decision:

In this case, the diagnosis of vasodepressor syncope was made by the [consulting physician] during the enrollee's hospitalization. The consulting physician stated that further diagnostic testing (i.e. head up tilt table testing) would "not add further diagnostic information." A treatment plan was developed at that time and discussed with the enrollee and his wife. Outpatient telemetry was then ordered on March 4, 2011 for the evaluation of syncope, although there is no documentation that the enrollee had further symptoms. Indeed, the outpatient telemetry monitor did not provide further useful information. Based upon the medical records presented here it does not appear that this test was necessary to establish the

diagnosis or effectiveness of treatment. The current guidelines for the management of patients with syncope recommend ECG monitoring in patients suspected of having arrhythmia-related syncope. This enrollee did not meet the criteria discussed in these guidelines.

Recommendation:

It is the recommendation of this reviewer that the denial of coverage issued by Blue Cross Blue Shield of Michigan, for the Mobile Cardiovascular Telemetry Surveillance, be upheld.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner finds that the mobile cardiac outpatient monitor is investigational/experimental for treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

V. ORDER

Respondent Blue Cross Blue Shield of Michigan's final adverse determination of July 8, 2011, is upheld. BCBSM is not required to cover the Petitioner's heart monitor.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner